

PATENT
0020-4841P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Wataru MORIKAWA et al. Conf.: Unknown
Appl. No.: 09/806,568 Group: Unknown
Filed: April 2, 2001 Examiner: UNKNOWN



For: ENZYME PRODUCING PLASMA PROTEIN
FRAGMENT HAVING INHIBITORY ACTIVITY TO
METASTASIS AND GROWTH OF CANCER AND
PLASMA PROTEIN FRAGMENT PRODUCED BY
FRAGMENTATION BY SAID ENZYME

INFORMATION DISCLOSURE STATEMENT
(SUBMISSION AFTER FILING OF AN APPLICATION
BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE
OR CONCURRENTLY WITH A RULE 53(d) CPA APPLICATION
OR WITH A RULE 1.114 RCE APPLICATION)

Assistant Commissioner for Patents
Washington, DC 20231

June 28, 2001

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-1449(s), attached hereto.

II. 'COPIES (check, at least one box)

- a. ☒ Submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. ☐ Some or all of the documents listed on the PTO-1449 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

III. CONCISE EXPLANATION OF THE RELEVANCE
(check at least one box)

a. ☐ **DOCUMENTS IN THE ENGLISH LANGUAGE**

The attached patents, publications, or other information in the English language do not require a statement of relevancy.

b. ☒ **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

Ohkoshi M.; Gan to Kagaku Ryoho, 1995 Mar; 22(4): 417-430 is cited on page 7, lines 15-16 of the specification. Also see the attached English abstract; Ohta T. et al.; Gan to Kagaku Ryoho, 1996 Oct; 23(12): 1669-1672 is cited on page 7, lines 14-15 of the specification. Also see the attached English abstract.

c. ☐ **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(A)(3).

d. ☒ **OTHER**

The following additional information is provided for the Examiner's consideration.

All of the attached references 1-16 (See Attachment) are discussed in the specification.

References 3, 6, 9 and 10 were also listed in the International Search Report.

Documents (1) to (16) are cited in the specification on the following relevant portions (the document number followed by page/line):

<u>Document Number</u>	<u>Page</u>	<u>Line(s)</u>
1	5	13-14
2	5	22-23
3	7	23-24
4	8	6-7
5	13	7-8
6	13	11-12
7	13	24-25
8	14	4-5
9	16	7-8
10	29	20-21
11	6	3-4
12	3	22-23
13	3	23-24
14	5	1-2
15	7	15-16
16	7	14-15

FEES

- IV. ☒ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b):
(check one box)
- a. ☒ within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. (This section is not to be used with RCE's and CPA's).
- b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.
- c. ☐ concurrently with the filing of a Continued Prosecution Application under 37 C.F.R. § 1.53(d) or concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

- d. ☐ before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

- V. ☐ THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

- a. ☐ No statement; therefore, a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).
or
b. ☐ See the statement below. No fee is required.

- VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. ☐ each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

- c. ☐ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VII. PAYMENT OF FEES (check one box)

- ☐ A check in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p) is enclosed for the above-identified fee.
- ☐ Please charge Deposit Account No. 02-2448 in the amount required by 37 C.F.R. § 1.17(p) for the above-indicated fee. A triplicate copy of this paper is attached.
- ☒ No fee is required.


If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 
Marc S. Weiner, #32,181

MSW/sh
0020-4841P

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Enclosures: ☒ PTO-1449
☒ Documents
☐ Foreign Search Report
☐ Fee
☒ Other: Attachment

ATTACHMENT

I D S on US Appl. No. 09/806, 568

- 1: Rak J, Mitsuhashi Y, Bayko L, Filmus J, Shirasawa S, Sasazuki T, Kerbel RS. Mutant ras oncogenes upregulate VEGF/VPF expression: implications for induction and inhibition of tumor angiogenesis. Cancer Res. 1995 Oct 15;55(20):4575-80.
- 2: Davies B, Brown PD, East N, Crimm MJ, Balkwill F. A synthetic matrix metalloproteinase inhibitor decreases tumor burden and prolongs survival of mice bearing human ovarian carcinoma xenografts. Cancer Res. 1993 May 1;53(9):2087-91.
- 3: O'Reilly MS, Holmgren L, Shing Y, Chen C, Rosenthal RA, Moses M, Lane WS, Cao Y, Sage EH, Folkman J. Angiostatin: a novel angiogenesis inhibitor that mediates the suppression of metastases by a Lewis lung carcinoma. Cell. 1994 Oct 21;79(2):315-28.
- 4: O'Reilly MS, Holmgren L, Chen C, Folkman J. Angiostatin induces and sustains dormancy of human primary tumors in mice. Nat Med. 1996 Jun;2(6):689-92.
- 5: Gately S, Twardowski P, Stack MS, Patrick M, Boggio L, Cundiff DL, Schnaper HW, Madison L, Volpert O, Bouck N, Enghild J, Kwaan HC, Soff GA. Human prostate carcinoma cells express enzymatic activity that converts human plasminogen to the angiogenesis inhibitor, angiostatin. Cancer Res. 1996 Nov 1;56(21):4887-90.
- 6: Soff GA, Sanderowitz J, Gately S, Verrusio E, Weiss I, Brem S, Kwaan HC. Expression of plasminogen activator inhibitor type 1 by human prostate carcinoma cells inhibits primary tumor growth, tumor-associated angiogenesis, and metastasis to lung and liver in an athymic mouse model.

J Clin Invest. 1995 Dec;96(6):2593-600.

7: Dong Z, Kumar R, Yang X, Fidler IJ. Macrophage-derived metalloelastase is responsible for the generation of angiostatin in Lewis lung carcinoma.

Cell. 1997 Mar 21;88(6):801-10.

8: Patterson BC, Sang QA. Angiostatin-converting enzyme activities of human matrilysin (MMP-7) and gelatinase B/type IV collagenase (MMP-9). J Biol Chem. 1997 Nov 14;272(46):28823-5.

9: Gately S, Twardowski P, Stack MS, Cundiff DL, Grella D, Castellino FJ, Enghild J, Kwaan HC, Lee F, Kramer RA, Volpert O, Bouck N, Soff GA. The mechanism of cancer-mediated conversion of plasminogen to the angiogenesis inhibitor angiostatin.

Proc Natl Acad Sci U S A. 1997 Sep 30;94(20):10868-72.

10: Briozzo P, Morisset M, Capony F, Rougeot C, Rochefort H. In vitro degradation of extracellular matrix with Mr 52,000 cathepsin D secreted by breast cancer cells.

Cancer Res. 1988 Jul 1;48(13):3688-92.

11: Wen-Tien Chen Membrane protease: roles in tissue remodeling and tumour invasion

Current Opin In Cell Biology 1992, 4:802-809.

12: Arnall Patz Studies on retinal neovascularization

Invest Ophthalmol. Vis. Sci. 1980, 19:1133-1138.

13: Patricia A. D'Amore and Robert W. Thompson Mechanisms of Angiogenesis

Ann. Rev. Physiol. 1987, 49:453-464.

- 14: William G. Stetler-Stevenson, Sadie Aznavoorian, and lance A. Liotta Tumor Cell Interactions with the Extracellular Matrix during Invasion and Metastasis
Annu. Rev. Cell Biol. 1993, 9:541-573.
- 15: Ohkoshi M. Protease Inhibitors as anticancer chemotherapy-experimental and clinical studies
Gan to Kagaku Ryoho, 1995 Mar; 22(4):417-430.
- 16: Ohta T, et al., Inhibitory effect of FOY-305 on liver metastasis of the pancreatic cancer
Gan to Kagaku Ryoho, 1996 Oct; 23(12):1669-1672.
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Form PTO-1449						ATTY DOCKET NO. 0020-4841P		APPLICATION NO. 09/806,568					
INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)						APPLICANT Wataru MORIKAWA et al.							
						FILING DATE April 2, 2001		GROUP Unknown / 642					
U.S. PATENT DOCUMENTS													
EXAMINER INITIAL		DOCUMENT NUMBER				DATE		NAME		CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
FOREIGN PATENT DOCUMENTS													
		DOCUMENT NUMBER				DATE		COUNTRY		CLASS	SUB CLASS	TRANSLATION YES NO	
OTHER DOCUMENTS (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.													
		J. Rak et al.; Cancer Research 55; pp. 4575-4580, October 15, 1995.											
		Bernard Davies et al.; Cancer Research 53; pp. 2087-2091, May 1, 1993.											
		Michael S. O'Reilly et al.; Cell, Vol. 79, pp. 315-328, October 21, 1994.											
		Michael S. O'Reilly et al.; Nature Medicine, Volume 2, Number 6, June 1996, pp. 689-692.											
		Stephen Gately et al.; Cancer Research 56, pp. 4887-4890, November 1, 1996.											
		Gerald A. Soff et al.; J. Clin. Invest., Vol. 96, December 1995; pp. 2593-2600.											
		Zhongyun Dong et al.; Cell. Vol. 88, pp. 801-810, March 21, 1997.											
		Brian C. Patterson et al.; The Journal of Biological Chemistry; Vol. 272, No. 46, November 14, 1997; pp. 28823-28825											
EXAMINER						DATE CONSIDERED							
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. include copy of this form with next communication to applicant.													

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0020-4841PAPPLICATION NO.
09/806,568INFORMATION DISCLOSURE CITATION
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(Use several sheets if necessary)

APPLICANT
Wataru MORIKAWA et al.FILING DATE
April 2, 2001GROUP
~~Unknown~~ 1642

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION
					YES NO

OTHER DOCUMENTS (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.

	Stephen Gately et al.; Proc. Natl. Acad. Sci. USA; Vol. 94, pp. 10868-10872; September 1997.
	P. Briozzo et al.; Cancer Research 48, pp. 3688-3692, July 1, 1988.
	Wen-Tien Chen; Current Opinion in Cell Biology 1992, 4; pp. 802-809.
	Arnall Patz; Invest. Ophthalmol. Vis. Sci.; 1980, Vol. 19, ppl 1133-1138
	Patricia A. D'Amore et al.; Ann. Rev. Physiol. 1987, 49, pp. 453-464.
	William G. Stetler-Stevenson et al.; Annu. Rev. Cell Biol., 1993 9:541-573.
	Ohkoshi M.; Gan to Kagaku Ryoho, 1995 March 22(4):417-30.
	Ohta T. et al.; Gan to Kagaku Ryoho, 1996 October 23(12):1669-72.

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